FEB 2 7 2012

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
K113231

This summary of the 510(k) safety and effectiveness information is be submitted in accordance with the requirements of 21 CFR 807.92.

Applicant: Quantum Devices, Inc.
112 Orbison Street
Barneveld, WI 53507

Phone: 608-924-3000
FAX: 608-924-3007

Contact Person: Glenn Ignatius
President
Quantum Devices, Inc.
112 Orbison Street
Barneveld, WI 53507

Phone: 608-924-3000
FAX: 608-924-3007

Prepared on: February 23, 2012

Model No./Name: Quantum WARP 75 Light Delivery Systems

Classification: Lamp, Infrared – 89 ILY
Physical Medicine Device, 21 CFR 890.5500

Description:

The Quantum WARP Light Delivery System (WARP-75) is used for applying therapy for the mitigation of chronic pain. Quantum Devices, Inc manufactures this light delivery system. These devices are solid state and hand held for placement directly over the skin where the treatment is to occur.

Statement of Intended Use for the WARP-75:

WARP-75 is a hand held device used for the treatment of chronic pain by emitting energy in the Near-IR spectrum for the temporary relief of minor muscle and joint pain, arthritis and muscle spasm; relieving stiffness; promoting relaxation of muscle tissue; to temporarily increase local blood circulation where applied.

Testing Summary:

Testing for the Quantum WARP 75 Light Delivery Systems has been carried out to ensure that the temperature at the skin surface where the device is applied is acceptable per IEC 60601-1 Part 42.3 (UL2601-1.

Substantial Equivalence:

The Quantum WARP 75 Light Delivery System is substantially equivalent to the Quantum WARP 10 Light Delivery System, K032229.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

FEB 2 7 2012

Quantum Devices, Inc.
% Waxler Regulatory Consultancy, LLC
Morris Waxler, Ph.D.
1920 Arlington Place
Madison, Wisconsin 53726

Re: K113231
Trade/Device Name: Quantum WARP 75 Light Delivery Systems
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: Class II
Product Code: ILY
Dated: February 15, 2012
Received: February 21, 2012

Dear Dr. Waxler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indication for Use

510(k) Number (if known): **K113231**

Device Name: Quantum WARP 75 Light Delivery Systems

Indications for Use:

WARP-75 is a hand held device used for the treatment of chronic pain by emitting energy in the Near-IR spectrum for the temporary relief of minor muscle and joint pain, arthritis and muscle spasm; relieving stiffness; promoting relaxation of muscle tissue; to temporarily increase local blood circulation where applied.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR ___X___Over-The-Counter Use
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K113231